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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/871,227	05/31/2001	Hector F. DeLuca	1256-00765	1698

7590

04/25/2003

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EXAMINER

BADIO, BARBARA P

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 04/25/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/871,227

Applicant(s)

DELUCA ET AL.

Examiner

Barbara P. Badio, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other:

**Final Office Action on the Merits**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Double Patenting***

m 2. The rejection of claims 1-4 and 9-32 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 7 and 12-20 of US Patent No. 5,945,410 is maintained.

Applicant's argument and the examiner's response are as discussed below in #4. It is also noted that although the reference exemplifies the lower adjacent homolog, it encompasses the claimed compound because it teaches (a) 2-alkyl derivatives wherein alkyl radical is 1 to 10 carbons and (b) "ethyl" as alkyl substituent in the 2-position (col. 5, lines 11-14, lines 44-49).

For these reasons and those given in Paper No. 8, the rejection of claims 1-4 and 9-32 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 7 and 12-20 of US Patent No. 5,945,410 is maintained.

m 3. The rejection of claims 5-8 and 33-56 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 7 and 12-16 of US Patent No. 5,843,928 is maintained.

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Applicant's argument and the examiner's response are similar to that discussed above in #2.

For these reasons and those given in Paper No. 8, the rejection of claims 5-8 and 33-56 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11, 2, 7 and 12-16 of US Patent No. 5,843,928 is maintained.

***Claim Rejections - 35 USC § 103***

u 4. **The rejection of claims 1-4 and 9-32 under 35 USC 103(a) over DeLuca et al. ('410) is maintained.**

Applicant argues that 2 $\alpha$ -ethyl-19-nor compound of the instant invention is both structurally and functionally different from the closest prior art compound. Applicant's argument was not persuasive for the following reasons.

Applicant argues that the claimed compounds are unobvious based on the data shown in Table 1 of the present specification and that shown in Table 1 of the cited reference. However, said comparison is not a true side-by-side comparison because it does not compare the closest prior art compound and the instantly claimed compound. In order to argue unexpected and/or unobvious results, comparison should be made between the closest prior art compound and the instantly claimed compound under identical conditions.

It is again noted that the reference teaches (a) a generic group of 2-alkyl-19-nor vitamin D compounds; (b) "alkyl" denotes an alkyl radical of 1 to 10 carbons and (c)

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"ethyl" as alkyl substituent in the 2-position. Based on the teachings of the prior art, the 2-ethyl derivative of the exemplified compound would have been obvious to the skilled artisan in the art at the time of the present invention.

For these reasons and those given in Paper No. 8, the rejection of claims 1-4 and 9-32 under 35 USC 103(a) over DeLuca et al. ('410) is maintained.

W 5. **The rejection of claims 5-8 and 33-56 under 35 USC 103(a) over DeLuca et al. ('928) is maintained.**

Applicant's argument and the examiner's response are similar to that discussed above in #4.

### ***Conclusion***

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

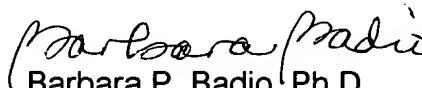
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***Telephone Inquiry***

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 7:30am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

  
Barbara P. Badio, Ph.D.  
Primary Examiner  
Art Unit 1616

BB  
April 23, 2003